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**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON**

MINDY BIRDWELL,

Plaintiff,

vs.

Case No.:
COMPLAINT WITH JURY DEMAND

AMERICAN MEDICAL SYSTEMS,
INC.; AMERICAN MEDICAL
SYSTEMS, LLC, INDIVIDUALLY
AND F/K/A AMERICAN MEDICAL
SYSTEMS, INC.; AMERICAN
MEDICAL SYSTEMS HOLDINGS,
INC.; ASTORA WOMEN'S
HEALTH, INC.; ASTORA
WOMEN'S HEALTH LLC; ASTORA
WOMEN'S HEALTH HOLDINGS,
LLC; ASTORA HOLDINGS, LLC,

Defendants.

I. CIVIL ACTION COMPLAINT

Plaintiff, MINDY BIRDWELL ("Plaintiff"), by and
through her counsel, brings this Complaint against
Defendants' AMERICAN MEDICAL SYSTEMS, INC., AMERICAN

1 MEDICAL SYSTEMS, LLC individually and f/k/a American
2 Medical Systems, Inc., AMERICAN MEDICAL SYSTEMS
3 HOLDINGS, INC., ASTORA WOMEN'S HEALTH, INC., ASTORA
4 WOMEN'S HEALTH LLC, ASTORA WOMEN'S HEALTH HOLDINGS LLC
5 and ASTORA HOLDINGS (collectively, "Defendants'", as
6 the context may require) for injuries suffered as a
7 result of defective pelvic mesh products designed,
8 manufactured and marketed by Defendants, and implanted
9 in Plaintiff. In support, Plaintiff states and avers
10 as follows:

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15 **II. PARTIES**

16 1. Plaintiff MINDY BIRDWELL, is, and was, at all
17 relevant times, a resident of the state of Oregon.

18 2. Defendant, American Medical Systems, Inc.
19 ("AMS) is a wholly owned subsidiary of Defendant
20 American Medical Systems Holdings Inc. and is a
21 foreign corporation with its principal offices in
22 Minnesota.

23 3. Defendant American Medical Systems, LLC,
24 ("AMS LLC") is a foreign corporation with its
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1 principal office in Delaware.

2 4. Defendant American Medical Systems Holdings
3 Inc., ("AMS HOLDINGS") is a foreign corporation with
4 its principal office in Minnesota.
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6 5. Defendant Astora Women's Health, Inc.,
7 ("ASTORA") was a foreign corporation with its
8 principal office in Minnesota.
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10 6. Defendant Astora Women's Health LLC, ("ASTORA
11 LLC") is a foreign corporation with its principal
12 office in Minnesota.
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14 7. Defendant Astora Women's Health Holdings, LLC,
15 ("ASTORA HOLDINGS LLC") is a foreign corporation
16 registered in Delaware.
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18 8. Defendant Astora Holdings, LLC ("ASTORA
19 HOLDINGS LLC") is a foreign corporation registered in
20 Delaware.
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22 9. Defendants share many of the same officers,
23 directors and operations; and maintain ownership in
24 the assets and/or liabilities relating to the design,
25 manufacture, marketing, distribution and sale of the
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1 medical device line at issue in this litigation and
2 shall be referenced collectively hereinafter as
3 "Defendants".
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5 10. All acts and omissions of each Defendant as
6 described herein were done by its agents, servants,
7 employees and/or owners, acting in the course and
8 scope of their respective agencies, services,
9 employments and/or ownership.
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12 **III. JURISDICTION AND VENUE**

13 11. Damages sought in this matter are in excess
14 of \$75,000.00. Subject matter jurisdiction is proper
15 pursuant to 28 U.S.C. § 1332.
16

17 12. This Court has subject matter jurisdiction
18 over the parties pursuant to 28 U.S.C. § 1332(a)
19 because the parties are citizens of different states
20 and the amount in controversy exceeds \$75,000.00,
21 exclusive of interest and costs.
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24 13. Venue is proper in the Eastern District Court
25 of Washington pursuant to 28 U.S.C. § 1391 because a
26 substantial part of the events giving rise to this
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1 claim occurred in this district.

2 14. Defendants conducted substantial business in
3 the State of Washington and in this District,
4 distribute Pelvic Mesh Products in this District,
5 receive substantial compensation and profits from
6 sales of Pelvic Mesh Products in this District, and
7 made material omissions and misrepresentations and
8 breaches of warranties in this District so as to
9 subject them to *in personam* jurisdiction in this
10 District.
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15 15. Defendants conducted business in the State of
16 Washington through sales representatives and because
17 Defendants were engaged in testing, developing,
18 manufacturing, labeling, marketing, distributing,
19 promotion and/or selling, either directly or
20 indirectly, and/or through third parties or related
21 entities, Pelvic Mesh Products; thus, there exists a
22 sufficient nexus between Defendant forum contacts and
23 the Plaintiff's claims to justify assertion of
24 jurisdiction in Washington.
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1 16. Consistent with the Due Process Clause of the
2 Fifth and Fourteenth Amendments, this Court has *in*
3 *personam* jurisdiction over Defendants, because
4 Defendants are present in the State of Washington such
5 that requiring an appearance does not offend
6 traditional notices of fair play and substantial
7 justice.
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11 **IV. DEFENDANTS' PELVIC MESH PRODUCTS**

12 17. At all times relevant herein, Defendants were
13 engaged in the business of placing medical devices
14 into the stream of commerce by designing,
15 manufacturing, marketing, packaging, labeling, and
16 selling such devices, including the Monarc Sling
17 System ("Monarc"). The Monarc is represented by
18 Defendants to correct and restore normal pelvic
19 function by implantation of polypropylene mesh in the
20 pelvis tethered in place by two arms that extend up
21 through a woman's pelvis. The Monarc was specifically
22 promoted to physicians and patients as an innovative,
23 minimally invasive procedure with minimal local tissue
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1 reactions, minimal tissue trauma, and minimal pain
2 while correcting urinary incontinence.
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4 18. Prior to the implantation of the Monarc at
5 issue in this claim, Defendants sought and obtained
6 Food and Drug Administration ("FDA") clearance to
7 market the Monarc under Section 510(k) of the Medical
8 Device Amendment to the Food, Drug and Cosmetics Act.
9 Section 510(k) allows marketing of medical devices if
10 the device is deemed substantially equivalent to other
11 legally marketed predicate devices marketed prior to
12 May 28, 1976. No formal review for safety or efficacy
13 is required.
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17 19. Despite claims that the monofilament
18 polypropylene mesh in the Monarc is inert, the
19 scientific evidence shows that this material is
20 biologically incompatible with human tissue and
21 promotes an immune response. This immune response
22 promotes degradation of the mesh material and can
23 contribute to the formation of severe adverse
24 reactions to the mesh.
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1 20. The Monarc was marketed to the medical
2 community and to patients as safe, effective, and
3 reliable medical devices that can be implanted by safe,
4 effective, and minimally invasive surgical techniques.
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6 21. Defendants marketed and sold the Monarc
7 through carefully planned, multifaceted marketing
8 campaigns and strategies. These campaigns and
9 strategies include, but are not limited to, aggressive
10 marketing and the provision of valuable cash and non-
11 cash benefits to healthcare providers. Defendants also
12 utilized documents, patient brochures, and websites,
13 offering exaggerated and misleading expectations as
14 to the safety, utility, and efficacy of the Monarc and
15 its other transvaginal mesh products.
16

17 22. Contrary to the representations and marketing
18 of Defendants, the Monarc has high failure, injury,
19 and complication rates, fails to perform as intended,
20 requires frequent and often debilitating revision
21 surgeries, and has caused severe and irreversible
22 injuries, conditions, and damage to a significant
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1 number of women, including Plaintiff Birdwell. The
2 defects stem from many issues, including:

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- 4 a. The use of polypropylene material in the Monarc
5 and the immune reaction that results;
- 6 b. the design of the Monarc to be inserted
7 transvaginally into an area of the body with
8 high levels of pathogens that adhere to the
9 mesh, which can cause immune reactions and
10 subsequent tissue breakdown;
- 11 c. the contraction and/or shrinkage of the mesh
12 and surrounding scar tissue;
- 13 d. biomechanical issues with the design of the
14 mesh that create strong amounts of friction
15 between the mesh and the underlying tissue that
16 subsequently cause that tissue to degrade and
17 the device to migrate into organs and
18 surrounding structures;
- 19 e. the use and design of anchors in the Monarc
20 that when placed correctly are likely to pass
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1 through and injure major nerve routes in the
2 pelvic region;

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4 f. degradation of the mesh itself over time which
5 causes the internal tissue to degrade;

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7 g. the welding of the mesh itself during
8 production, which creates a toxic substance
9 that contributes to the degradation of the mesh
10 and host tissue; and

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12 h. the design of the trocars (devices used to
13 insert the Monarc into the vagina) requires
14 tissue penetration in nerve-rich environments,
15 which results frequently in the destruction of
16 nerve endings.
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19 23. Upon information and belief, Defendants has
20 consistently underreported and withheld information
21 about the propensity of its Monarc to fail and to
22 cause injury and complications and has misrepresented
23 the efficacy and safety of its transvaginal mesh
24 products, including the Monarc, through various means
25 and media, actively and intentionally misleading the
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1 public.

2 24. Despite the chronic underreporting of adverse
3 events associated with the Monarc, enough complaints
4 were recorded for the Food and Drug Administration
5 ("FDA") to issue a public health notification
6 regarding the dangers of these devices.
7

8 25. On October 20, 2008, the FDA issued a Public
9 Health Notification that described over a thousand
10 (1,000) complaints (otherwise known as "adverse
11 events") that had been reported over a three-year
12 period relating to the Monarc and other similar
13 products. Although the FDA notice did not identify the
14 transvaginal mesh manufacturers by name, a review of
15 the FDA's MAUDE database indicates that Defendants is
16 one of the manufacturers of the products that are the
17 subject of the notification.
18

19 26. On July 13, 2011, the FDA issued a Safety
20 Communication entitled, "UPDATE on Serious
21 Complications Associated with Transvaginal Placement
22 of Surgical Mesh for Pelvic Organ Prolapse." Therein,
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1 the FDA advised that it had conducted an updated
2 analysis of adverse events reported to the FDA and
3 complications reported in the scientific literature
4 and concluded that surgical mesh used in transvaginal
5 repair of pelvic organ prolapse was an area of
6 "continuing serious concern." (emphasis added) The FDA
7 concluded that serious complications associated with
8 surgical mesh for transvaginal repair of pelvic organ
9 prolapse were "not rare." These serious complications
10 include, but are not limited to, neuromuscular
11 problems, vaginal scarring/shrinkage, and emotional
12 problems. Many of the serious complications required
13 medical and surgical treatment and hospitalization.
14 The FDA concluded that it was not clear that
15 transvaginal repair of pelvic organ prolapse and
16 stress urinary incontinence with mesh kits was more
17 effective than traditional non-mesh repair of these
18 conditions. The FDA conducted a systematic review of
19 the published scientific literature from 1996 to 2011
20 and concluded that transvaginal pelvic organ prolapse
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1 repair with mesh "does not improve symptomatic results
2 or quality of life over traditional non mesh repair."
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4 In the July 13, 2011 Safety Communication, the FDA
5 concluded that "a mesh procedure may put the patient
6 at risk for requiring additional surgery or for the
7 development new complications. Removal of the mesh due
8 to mesh complications may involve multiple surgeries
9 and significantly impair the patient's quality of life.
10 Complete removal of mesh may not be possible." The
11 information contained in the FDA's Public Health
12 Notification of October 2008 and the FDA Safety
13 Communication of July 13, 2011 was known or knowable
14 to Defendants and was not disclosed in any manner.
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19 27. Defendants have further known the following:

20 a. that some of the predicate devices for the
21 Monarc had high failure and complication
22 rates, resulting in the recall of some of these
23 predicate devices;
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26 b. that there were and are significant
27 differences between the Monarc and some or all
28

1 of the predicate devices, rendering them
2 unsuitable for designation as predicate
3 devices;
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5 c. that these significant differences render the
6 disclosures to the FDA incomplete and
7 misleading; and
8

9 d. that its transvaginal mesh products, including
10 thee Monarc, were and are causing numerous
11 patients severe injuries and complications.
12

13 28. Defendants suppressed this information and
14 failed to accurately and completely disseminate or
15 share this and other critical information with others,
16 including Plaintiff Birdwell. As a result, Defendants
17 actively and intentionally misled and continues to
18 mislead the public into believing that its
19 transvaginal mesh products, including the Monarc, and
20 the procedures for implantation were and are safe and
21 effective.
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26 29. Defendants failed to perform or rely on
27 proper and adequate testing and research in order to
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1 determine and evaluate the risks and benefits of the
2 Monarc.
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4 30. Defendants failed to design and establish a
5 safe, effective procedure for removal of the Monarc;
6 thus, in the event of a failure, injury, or
7 complications, it is impossible to easily and safely
8 remove the Monarc or parts thereof.
9

10 31. Feasible and suitable alternative designs as
11 well as suitable alternative procedures and
12 instruments for repair of pelvic organ prolapse and
13 stress urinary incontinence have existed at all times
14 relevant to this matter.
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16 32. The Monarc was at all times utilized and
17 implanted in a manner foreseeable to Defendants, as
18 they generated the instructions for use, created the
19 procedures for implanting the devices, and trained the
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1 Monarc, and thus increase the sales of these products.

2 34. The Monarc implanted into Plaintiff Birdwell
3 was in the same or substantially similar condition as
4 when it left the possession of Defendants, as well as
5 being in the condition directed by and expected by
6 this Defendant.
7

8 35. Plaintiff Birdwell and her physicians
9 foreseeably used and implanted the Monarc, and did not
10 misuse or alter these products in an unforeseeable
11 manner.
12

13 36. The injuries, conditions, and complications
14 suffered by women who have been implanted with the
15 Monarc include, but are not limited to, mesh erosion,
16 mesh contraction, infection, fistula, inflammation,
17 scar tissue, organ perforation, dyspareunia (pain
18 during sexual intercourse), blood loss, acute and
19 chronic nerve damage and pain, pudendal nerve damage,
20 pelvic floor damage, chronic pelvic pain, urinary and
21 fecal incontinence, recurrent and chronic infections,
22 and prolapse of organs. In many cases, these women
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1 have been forced to undergo intensive medical
2 treatment, including, but not limited to, the use of
3 pain control and other medications, injections into
4 various areas of the pelvis, spine, and the vagina,
5 and surgeries to remove portions of the female
6 genitalia, to locate and remove mesh, and to attempt
7 to repair pelvic organs, tissue, and nerve damage.
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11 37. The medical and scientific literature
12 studying the effects of polypropylene pelvic mesh
13 (like the material used in the Monarc) have examined
14 each of these injuries, conditions, and complications
15 and determined that they are in fact casually related
16 to the mesh itself and do not often implicate errors
17 related to the implantation of the devices.
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21 38. Defendants knew and had reason to know that
22 the Monarc could and would cause severe and grievous
23 personal injury to the users/recipients of the Monarc,
24 and that they were inherently dangerous in a manner
25 that exceeded any purported, inaccurate, or otherwise
26 downplayed warnings.
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1 39. At all relevant times herein, Defendants
2 continued to promote Monarc as safe and effective even
3 when no clinical trials had been done supporting long
4 or short term efficacy.
5

6 40. At all relevant times herein, Defendants
7 failed to provide sufficient warnings and instructions
8 that would have put Plaintiff Birdwell and the public
9 on notice of the dangers and adverse effects caused
10 by implantation of the Monarc.
11

12 41. The Monarc was defective as marketed due to
13 inadequate warnings, instructions, labeling, and/or
14 inadequate testing.
15

16 42. The products known as Monarc, as well as any
17 as yet unidentified pelvic mesh products designed and
18 sold for similar purposes, inclusive of the
19 instruments and procedures for implantation, are
20 collectively referenced herein as Defendants' Pelvic
21 Mesh Products or the Pelvic Mesh Products.
22

23 43. Defendants' Pelvic Mesh Products were
24 designed, patented, manufactured, labeled, marketed,
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1 and sold and distributed by the Defendants, at all
2 times relevant herein.
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4 **V. FACTUAL BACKGROUND**

5 44. On July 8, 2010, Plaintiff was implanted with
6 an AMS Monarc, Lot No. 65842208, Ref No. 72403830,
7 ("Monarc" or "Pelvic Mesh Product", and/or "Product")
8 during surgery performed at Providence St. Mary
9 Medical Center in Walla Walla, Washington.
10
11

12 45. The Pelvic Mesh Products were implanted in
13 Plaintiff to treat her pelvic organ prolapse, the use
14 for which the Pelvic Mesh Products were designed,
15 marketed and sold.
16

17 46. On June 27, 2020, Plaintiff underwent
18 revision surgery of the AMS Monarc at Providence St.
19 Mary Medical Center in Walla Walla, Washington.
20
21

22 47. As a result of having the Product implanted
23 in her, Plaintiff has experienced significant mental
24 and physical pain and suffering, has sustained
25 permanent injury and permanent and substantial
26 physical deformity and has suffered financial or
27
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1 economic loss, including, but not limited to,
2 obligations for medical services and expenses.
3

4 48. Defendants' Pelvic Mesh Product has been and
5 continues to be marketed to the medical community and
6 to patients as a safe, effective, reliable, medical
7 device; implanted by safe and effective, minimally
8 invasive surgical techniques for the treatment of
9 medical conditions, primarily pelvic organ prolapse
10 and stress urinary incontinence, and as safer and more
11 effective as compared to the traditional products and
12 procedures for treatment, and other competing pelvic
13 mesh products.
14
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16

17 49. The Defendants have marketed and sold the
18 Defendants' Pelvic Mesh Product to the medical
19 community at large and patients through carefully
20 planned, multifaceted marketing campaigns and
21 strategies. These campaigns and strategies include,
22 but are not limited to direct to consumer advertising,
23 aggressive marketing to health care providers at
24 medical conferences, hospitals, private offices, and
25
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28

1 include the provision of valuable consideration and
2 benefits to health care providers. Also utilized are
3 documents, brochures, websites, and telephone
4 information lines, offering exaggerated and
5 misleading expectations as to the safety and utility
6 of the Defendants' Pelvic Mesh Product.
7

8
9 50. Contrary to the Defendants' representations
10 and marketing to the medical community and to the
11 patients themselves, the Defendants' Pelvic Mesh
12 Product has high failure, injury, and complication
13 rates, fails to perform as intended, requires frequent
14 and often debilitating re-operations, and has caused
15 severe and irreversible injuries, conditions, and
16 damage to a significant number of women, including the
17 Plaintiff.
18
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21

22 51. The Defendants have consistently
23 underreported and withheld information about the
24 propensity of Defendants' Pelvic Mesh Product to fail
25 and cause injury and complications, and have
26 misrepresented the efficacy and safety of the Product,
27
28

1 through various means and media, actively and
2 intentionally misleading the FDA, the medical
3 community, patients, and the public at large.
4

5 52. Defendants have known and continue to know
6 that their disclosures to the FDA were and are
7 incomplete and misleading; and that the Defendants'
8 Pelvic Mesh Product was and is causing numerous
9 patients' severe injuries and complications. The
10 Defendants suppressed this information and failed to
11 accurately and completely disseminate or share this
12 and other critical information with the FDA, health
13 care providers, or the patients. As a result, the
14 Defendants actively and intentionally misled and
15 continue to mislead the public, including the medical
16 community, health care providers and patients, into
17 believing that the Defendants' Pelvic Mesh Product was
18 and is safe and effective, leading to the prescription
19 for and implantation of the Pelvic Mesh Product into
20 the Plaintiff.
21
22
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27 53. Defendants failed to perform or rely on
28

1 proper and adequate testing and research in order to
2 determine and evaluate the risks and benefits of the
3 Defendants' Pelvic Mesh Product.
4

5 54. Defendants failed to design and establish a
6 safe, effective procedure for removal of the
7 Defendants' Pelvic Mesh Product; therefore, in the
8 event of a failure, injury, or complications it is
9 impossible to easily and safely remove the Defendants'
10 Pelvic Mesh Product.
11
12

13 55. Feasible and suitable alternative designs as
14 well as suitable alternative procedures and
15 instruments for implantation and treatment of stress
16 urinary incontinence, pelvic organ prolapse, and
17 similar other conditions have existed at all times
18 relevant as compared to the Defendants' Pelvic Mesh
19 Product.
20
21
22

23 56. The Defendants' Pelvic Mesh Product was at
24 all times utilized and implanted in a manner
25 foreseeable to the Defendants.
26

27 57. The Defendants have at all times provided
28

1 incomplete, insufficient, and misleading training and
2 information to physicians, in order to increase the
3 number of physicians utilizing the Defendants' Pelvic
4 Mesh Product, and thus increase the sales of the
5 Product, and also leading to the dissemination of
6 inadequate and misleading information to patients,
7 including Plaintiff.

10
11 58. The Pelvic Mesh Product implanted into the
12 Plaintiff was in the same or substantially similar
13 condition as it was when it left the possession of
14 Defendants, and in the condition directed by and
15 expected by the Defendants.

17
18 59. The injuries, conditions, and complications
19 suffered due to Defendants' Pelvic Mesh Product
20 include but are not limited to mesh erosion, mesh
21 contraction, infection, fistula, inflammation, scar
22 tissue, organ perforation, dyspareunia, blood loss,
23 neuropathic and other acute and chronic nerve damage
24 and pain, pudendal nerve damage, pelvic floor damage,
25 pelvic pain, urinary and fecal incontinence, prolapse
26
27
28

1 of organs, and in many cases the women have been forced
2 to undergo intensive medical treatment, including but
3 not limited to operations to locate and remove mesh,
4 operations to attempt to repair pelvic organs, tissue,
5 and nerve damage, the use of pain control and other
6 medications, injections into various areas of the
7 pelvis, spine, and the vagina, and operations to
8 remove portions of the female genitalia, and injuries
9 to Plaintiff's intimate partners.
10
11
12

13 60. Despite Defendants' knowledge of these
14 catastrophic injuries, conditions, and complications
15 caused by their Pelvic Mesh Product, the Defendants
16 have, and continue to manufacture, market, and sell
17 the Product, while continuing to fail to adequately
18 warn, label, instruct, and disseminate information
19 with regard to the Defendants' Pelvic Mesh Product,
20 both prior to and after the marketing and sale of the
21 Product.
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VI. FIRST CAUSE OF ACTION
WASHINGTON PRODUCT LIABILITY ACT

61. Plaintiffs incorporate by reference all prior paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

62. At all times relevant to this litigation, Defendant engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting its medical device products.

63. At all times relevant to this litigation, Defendant designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, and distributed the medical device used by Plaintiff as described above.

64. At all times relevant to this litigation, Defendant's medical device was expected to reach and did reach the intended consumers, handlers, and users or other persons coming into contact with these

1 products in Washington and throughout the United
2 States, including Plaintiffs, without substantial
3 change in their condition as designed, manufactured,
4 sold, distributed, labeled, and marketed by Defendant.
5

6 65. In violation of the Washington Products
7 Liability Act ("WPLA"), RCW 7.72, et seq., at all
8 times relevant to this action, at the time Defendant's
9 medical device left control of Defendant, it was
10 defective and not reasonably safe. These defects
11 include, but are not limited to, the following:
12
13
14

- 15 a) Defendant is strictly liable for
16 Plaintiffs' injuries and damages
17 because at the time of manufacture, and
18 at the time Defendant's medical device
19 left control of Defendant, the
20 likelihood that the medical device
21 would cause injury or damage similar to
22 that suffered by Plaintiffs, and the
23 seriousness of such injury or damage had
24 been known by Defendant and outweighed
25 the burden on Defendant to design a
26 product that would have prevented
27 Plaintiffs' injuries and damages and
28 outweighed the adverse effect that an
alternative design that was practical
and feasible would have on the
usefulness of the subject product.

1 b) Defendant's medical device is unsafe to
2 an extent beyond that which would be
3 contemplated by an ordinary consumer.

4 c) The medical device manufactured and/or
5 supplied by Defendant was defective in
6 design in that, an alternative design
7 and/or formulation exists that would
8 prevent severe and permanent injury.
9 Indeed, at the time that Defendant
10 designed its medical device, the state
11 of the industry's scientific knowledge
12 was such that a less risky design or
13 formulation was attainable.

14 d) The medical device was not reasonably
15 safe in design under the WPLA.

16 e) The medical device manufactured and/or
17 supplied by Defendant was not
18 reasonably safe because Defendant did
19 not provide an adequate warning or
20 instruction about the product. At the
21 time the medical device left
22 Defendant's control, the device
23 possessed dangerous characteristics and
24 Defendant failed to use reasonable care
25 to provide an adequate warning of such
26 characteristics and their danger to
27 users and handlers of the product. The
28 medical device is not safe and cause
severe and permanent injuries. The
medical device was not reasonably safe
because the warning was inadequate, and
Defendant could have provided adequate
warnings or instructions.

f) The medical device that was
manufactured and/or supplied by

1 Defendant was not reasonably safe
2 because adequate warnings or
3 manufacturer instructions were not
4 provided after the medical device was
5 manufactured and when Defendant learned
6 of, or should have learned of, the
dangers connected with the medical
device.

7 g) The medical device manufactured and/or
8 supplied by Defendant was not
9 reasonably safe because it did not
10 conform to an express warranty made by
11 Defendant regarding the product's
12 safety and fitness for use. Defendant
13 expressly warranted that the medical
14 device was safe and fit for their
15 intended purposes, that it was of
16 merchantable quality, that it was not
17 produce any dangerous side effects,
18 that they were adequately tested, and
19 that the device was safe to human health
20 and the environment, and effective, fit,
21 and proper for its intended
22 use. Defendant did not disclose the
23 material risks that its medical device
24 could cause severe and permanent injury.
25 Defendant's express warranty induced
Plaintiff to use the device, and
Plaintiff's damages were proximately
caused because Defendant's express
warranty was untrue. The mesh product
was not reasonably safe because of
nonconformity to express warranty under
the WPLA.

26 66. As a direct and proximate result of Defendant
27 placing its defective medical device into the stream
28

1 of commerce, Plaintiff suffered grave injuries, and
2 endured physical and emotional pain and discomfort,
3 as well as economic hardship, including considerable
4 financial expenses for medical care and treatment and
5 other damages further discussed in herein.
6
7

8 WHEREFORE, Plaintiff demands judgment against
9 Defendants, and each of them, individually, jointly,
10 severally and in the alternative, and request
11 compensatory damages, punitive damages, together with
12 interest, costs of suit, attorneys' fees, and such
13 further relief as the Court deems equitable and just.
14
15

16 **VII. SECOND CAUSE OF ACTION**
17 **VIOLATION OF THE WASHINGTON CONSUMER PROTECTION**

18 **ACT**
19

20 67. Plaintiff realleges and incorporates by
21 reference every allegation of this Complaint as if
22 each were set forth fully and completely herein.
23

24 68. Plaintiff purchased and used the Defendants'
25 Pelvic Mesh Product primarily for personal use and
26 thereby suffered ascertainable losses as a result of
27
28

1 Defendants' actions in violation of the consumer
2 protection laws.
3

4 69. Had Defendants not engaged in the deceptive
5 conduct described herein, Plaintiff would not have
6 purchased and/or paid for the Defendants' Pelvic Mesh
7 Product, and would not have incurred related medical
8 costs and injury.
9

10 70. Defendants engaged in wrongful conduct while
11 at the same time obtaining, under false pretenses,
12 moneys from Plaintiff for the Pelvic Mesh Product that
13 would not have been paid had Defendants not engaged
14 in unfair and deceptive conduct.
15

- 16
- 17 a) Unfair methods of competition or
18 deceptive acts or practices that were
19 proscribed by law, including the
20 following:
 - 21 b) Representing that goods or services
22 has characteristics, ingredients, uses
23 benefits or quantities that they do
24 not have;
 - 25 c) Advertising goods or services with the
26 intent not to sell them as advertised;
27 and,
28

- 1 d) Engaging in fraudulent or deceptive
2 conduct that creates a likelihood of
3 confusion or misunderstanding.

4 71. Plaintiff was injured by the cumulative and
5 indivisible nature of Defendants' conduct. The
6 cumulative effect of Defendants' conduct directed at
7 patients, physicians and consumers was to create
8 demand for and sell the Defendants' Pelvic Mesh
9 Product. Each aspect of Defendants' conduct combined
10 to artificially create sales of the Defendants' Pelvic
11 Mesh Product.
12 Mesh Product.

13 72. Defendants have a statutory duty to refrain
14 from unfair or deceptive acts or trade practices in
15 the design, labeling, development, manufacture,
16 promotion, and sale of the Defendants' Pelvic Mesh
17 Product.
18 Product.

19 73. Had Defendants not engaged in the deceptive
20 conduct described above, Plaintiff would not have
21 purchased and/or paid for the Product, and would not
22 have incurred related medical costs.
23 have incurred related medical costs.

24 74. Defendants' deceptive, unconscionable, or
25 deceptive, unconscionable, or
26 deceptive, unconscionable, or
27 deceptive, unconscionable, or
28 deceptive, unconscionable, or

1 fraudulent representations and material omissions to
2 patients, physicians and consumers, including
3 Plaintiff, constituted unfair and deceptive acts and
4 trade practices in violation of the state consumer
5 protection statutes listed.
6
7

8 75. Defendants' actions, as complained of herein,
9 constitute unfair competition or unfair,
10 unconscionable, deceptive or fraudulent acts, or trade
11 practices in violation of state consumer protection
12 statutes, as listed below.
13
14

15 76. Defendants have engaged in unfair competition
16 or unfair or deceptive acts or trade practices or have
17 made false representations.
18

19 77. Under applicable state statutes enacted to
20 protect consumers against unfair, deceptive,
21 fraudulent and unconscionable trade and business
22 practices and false advertising, Defendants are the
23 suppliers, manufacturers, advertisers, and sellers,
24 who are subject to liability under such legislation
25 for unfair, deceptive, fraudulent and unconscionable
26
27
28

1 consumer sales practices.

2 78. Defendants violated the statutes that were
3 enacted in these states to protect consumers against
4 unfair, deceptive, fraudulent and unconscionable
5 trade and business practices and false advertising,
6 by knowingly and falsely representing that the
7 Defendants' Pelvic Mesh Product was fit to be used for
8 the purpose for which it was intended, when in fact
9 it was defective and dangerous, and by other acts
10 alleged herein. These representations were made in
11 marketing and promotional materials.

16 79. The actions and omissions of Defendants
17 alleged herein are uncured or incurable deceptive acts
18 under the statutes enacted in the states to protect
19 consumers against unfair, deceptive, fraudulent and
20 unconscionable trade and business practices and false
21 advertising.

24 80. Defendants had actual knowledge of the
25 defective and dangerous condition of the Defendants'
26 Pelvic Mesh Product and failed to take any action to
27

1 cure such defective and dangerous conditions.

2 81. Plaintiff and the medical community relied
3 upon Defendants' misrepresentations and omissions in
4 determining which product and/or procedure to undergo
5 and/or perform (if any).
6
7

8 82. Defendants' deceptive, unconscionable or
9 fraudulent representations and material omissions to
10 patients, physicians and consumers, constituted
11 unfair and deceptive acts and practices.
12

13 83. By reason of the unlawful acts engaged in by
14 Defendants, and as a direct and proximate result
15 thereof, Plaintiff has suffered ascertainable losses
16 and damages.
17
18

19 84. As a direct and proximate result of
20 Defendants' violations of the states' consumer
21 protection laws, Plaintiff has sustained economic
22 losses and other damages and is entitled to statutory
23 and compensatory, damages in an amount to be proven
24 at trial.
25
26

27 WHEREFORE, Plaintiff demands judgment against
28

1 Defendants, and each of them, individually, jointly,
2 severally and in the alternative, and request
3 restitution and disgorgement of profits, together with
4 interest, cost of suit, attorneys' fees, and all such
5 other and further relief as this Court deems just and
6 proper.
7

8
9 **VIII. PUNITIVE DAMAGES**

10
11 85. Plaintiff realleges and incorporates by
12 reference every allegation of this Complaint as if
13 each were set forth fully and completely herein.
14

15 86. The wrongs done by Defendants were aggravated
16 by the kind of malice, fraud, and grossly negligent
17 disregard for the rights of others, the public, and
18 Plaintiff for which the law would allow, and which
19 Plaintiff will seek at the appropriate time under
20 governing law for the imposition of exemplary damages,
21 in that Defendants' conduct, including the failure to
22 comply with applicable Federal standards: was
23 specifically intended to cause substantial injury to
24 Plaintiff; or when viewed objectively from Defendants'
25
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28

1 standpoint at the time of the conduct, involved an
2 extreme degree of risk, considering the probability
3 and magnitude of the potential harm to others, and
4 Defendants were actually, subjectively aware of the
5 risk involved, but nevertheless proceeded with
6 conscious indifference to the rights, safety, or
7 welfare of others; or included a material
8 representation that was false, with Defendants,
9 knowing that it was false or with reckless disregard
10 as to its truth and as a positive assertion, with the
11 intent that the representation is acted on by
12 Plaintiff.

13
14
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18 87. Plaintiff relied on the representation and
19 suffered injury as a proximate result of this reliance.

20
21 88. Plaintiff therefore will seek to assert
22 claims for exemplary damages at the appropriate time
23 under governing law in an amount within the
24 jurisdictional limits of the Court.

25
26 89. Plaintiff also alleges that the acts and
27 omissions of named Defendants, whether taken
28

1 singularly or in combination with others, constitute
2 gross negligence that proximately caused the injuries
3 to Plaintiff. In that regard, Plaintiff will seek
4 exemplary damages in an amount that would punish
5 Defendants for their conduct and which would deter
6 other manufacturers from engaging in such misconduct
7 in the future.
8
9

10 WHEREFORE, Plaintiff demands judgment against
11 Defendants, and each of them, individually, jointly,
12 severally and in the alternative, and request
13 compensatory damages, together with interest, costs
14 of suit, attorneys' fees, and such further relief as
15 the Court deems equitable and just.
16
17
18

19 **IX. PRAYER FOR RELIEF**

20 WHEREFORE, Plaintiff demands judgment against
21 Defendants, and each of them, individually, jointly
22 and severally and requests compensatory damages,
23 together with interest, cost of suit, attorneys' fees,
24 and all such other relief as the Court deems just and
25 proper as well as:
26
27
28

- 1 A. All general, statutory, and compensatory
2 damages, in excess of the amount required for
3 federal diversity jurisdiction, and in an
4 amount to fully compensate Plaintiff for all
injuries and damages, both past and present;
- 5 B. All special and economic damages, in excess
6 of the amount required for federal diversity
7 jurisdiction and in an amount to fully
8 compensate Plaintiff for all of her injuries
and damages, pain and suffering;
- 9 C. Attorneys' fees, expenses, and costs of this
10 action;
- 11 D. Double or triple damages as allowed by law;
- 12 E. Punitive and/or exemplary damages;
- 13 F. Pre-judgment and post-judgment interest in
14 the maximum amount allowed by law; and
- 15 G. Such further relief as this Court deems
16 necessary, just, and proper.

17 **X. DEMAND FOR JURY TRIAL**

18 Plaintiff demands a trial by jury on all issues
19
20 so triable.

21 //

22 //

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27 //

1 Dated this 15th day of March, 2022.

2 CORRIE YACKULIC LAW FIRM, PLLC

3
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